K080553

APR 16 2008

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Jan. 20, 2008

1. Company and Correspondent making the submission:

Name – Vieworks Co., Ltd.
Address – #604, Suntechcity 2, 307-2, Sangdaewon-dong, Jungwon-gu, Seongnam-city, Gyeonggi-do, 462-725 South Korea
Telephone – +82-70-7011-6190
Fax – +82-31-737-4954
Contact – Raza, Kim / Sales & Marketing Manager
E-mail – Cmk789@vieworks.com

2. Device :

Trade/proprietary name	: QXR-16
Common Name	: Digital Radiography System
Classification Name	: System, x-ray, stationary

3. Predicate Devices :

Manufacturer	: Vieworks Co.,Ltd.
Device	: QXR-9
510(k) Number	: K073056(Decision Date – 11. 13. 2007)

4. Classifications Names & Citations :

21CFR 892.1680, KPR - System, x-ray, stationary, Class 2

5. Description :

5.1 General

The QXR-16 Digital Radiography Systems is a high-resolution digital imaging system designed for digital radiography. It is designed to replace conventional

film radiography techniques. This system consists of Detector, Power Supply Unit, Accessories, and S/W. The S/W is operated at a workstation that is using Windows XP based OS as its operating system.
The system allows the operator to acquire and display images(Image size : 4096x4096 pixels) on 1600 x1200 high resolution monitor.

Various features of S/W such as image inversion, image processing, zooming, panning, window level adjustment, contrast adjustment etc enable the operator to view diagnostic details difficult to see using conventional non-digital techniques.

5.2 Features

- One Charge Coupled Device (CCD) armed with one lens.
- 17" x17" imaging area with 4096 x 4096 image format.
- High resolution image with 4.6lp/mm
- Wide dynamic range with 14-bit digitization
- S/W is designed to be operated on MS Windows XP operating system
- Image process parameters are selectable according to the body part to make best images for diagnosis
- Make copy of images to a CD or DVD or an external USB storage
- No x-ray generator control
- DICOM3.0 standard compliance
- DICOM printer and laser printer compatible
- Image Acquisition within 3.5 seconds after x-ray exposure
- Display processed image within 16 seconds after x-ray exposure
- Non-Processed image can be displayed by using Preview function

6. Indication for use :

QXR-16 Digital Radiography system is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

7. Comparison with predicate device :

Vieworks Co., Ltd. believes that the Digital Radiography System (QXR-16) is substantially equivalent to to QXR-9 of Vieworks Co.,Ltd. and AddOn Multi System of Swissray International, Inc..

8. Safety, EMC, Biocompatibility and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 and IEC 60601-1-1 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001).

Biocompatibility testing was conducted in accordance with Standard ISO 10993-1.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" was performed.

All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Vieworks Co., Ltd. concludes that the Digital Radiography System(QXR-16) is safe and effective and substantially equivalent to predicate devices as described herein.

10. Vieworks Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

#604, Suntechcity 2, 307-2, Sangdaewon-dong, Jungwon-gu,
Seongnam-city, Gyeonggi-do, 462-725 South Korea

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 2008

Vieworks Co., Ltd.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Accredited Person Program
Underwriters Laboratories, Inc.
455 E. Trimble Road
SAN JOSE CA 95131-1230

Re: K080553
Trade/Device Name: Digital Radiography System QXR-16
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: March 27, 2008
Received: April 1, 2008

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K080553

Device Name: Digital Radiography System/ QXR-16

Indications for Use:

QXR-16 Digital Radiography system is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080553